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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,533	07/10/2001	Chong Jin Oon	U 013108-9	8503

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NEW YORK, NY 10023

EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,533	Applicant(s) OON ET AL.	
	Examiner Donna C. Wortman, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 1, 13 and 15-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 34 and 37 were amended in the paper filed 29 September 2003.

Applicant's election with traverse of Group II, claims 2-9, 12 and 14 in the paper filed 29 September 2003 is acknowledged. The traversal is on the grounds (1) that the nucleic acids of claims 10 and 11 are subsequences of the nucleic acid of Group II and should be placed in Group II, and (2) that under lack of unity, applicants are entitled to claims to purified polypeptide encoded by the nucleic acid and claims directed to a use of the nucleic acid, i.e., claims 21, 23 and the claims of Group XIV.

On further consideration, claims 10 and 11 have been placed in Group II.

Applicant's remarks under (2), above, are not found persuasive because lack of unity is evaluated with respect to the main invention, i.e., the invention appearing in claim 1; the strain of claim 1 is not required by any of the other inventions as set forth in the requirement for restriction/election. Further, the elected invention is not seen to make a contribution over the prior art as set forth below. There is no unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-12 and 14 are under examination. Claims 1, 13, and 15-74 are withdrawn from consideration as drawn to non-elected inventions.

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 does not further limit the subject matter of claim 3 because claim 3 recites a sequence that comprises "AGA" at positions 587-589.

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite in reciting "substantially the same" which expression is not defined in the specification. Lacking a definition, one of skill in the art would not be reasonably apprised of the scope of the claim since one would not know how similar two amino acid sequences would have to be in order to be "substantially the same."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 5-9, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/14703, cited on PTO 892. WO 91/14703 teaches cloning and expression of HBV DNA that codes for HBsAg with an arginine for glycine substitution at position 145, anticipating the subject matter of claims 2, 5-9, 12 and 14.

Claims 2-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Oon et al., of record. Oon et al. disclose the vaccine escape mutant of a Singapore strain of hepatitis B that has a Gly-to-Arg substitution at amino acid position 145 and the extraction of the viral DNA (see paragraph bridging pages 701-702); the disclosure clearly anticipates claims 2, 5, and 8. Oon et al. is also deemed to anticipate the subject matter of claim 9 since, in the absence of any other definition, "substantially the

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same" is interpreted to mean the same as the sequence of any vaccine escape mutant of a Singapore strain of hepatitis B. Further, since Applicant discloses nucleic acid sequence from a Singapore strain of hepatitis B with a Gly-to-Arg substitution at amino acid position 145, and Oon et al. disclose DNA from a Singapore strain of hepatitis B with a Gly-to-Arg substitution at amino acid position 145, and since nucleotide sequence and encoding capability are inherent properties of viral DNA, in the absence of evidence to the contrary, the DNA disclosed by Oon et al. is deemed to be the same as the nucleic acid of claims 3, 4, 10 and 11, where claims 10 and 11 are interpreted as reading on the larger nucleic acid of which each recites a subsequence, since both "has" and "comprising" are interpreted as open language.

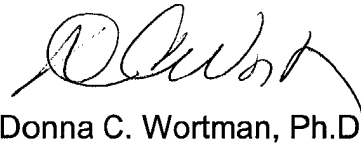
Claims 6, 7, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oon et al. in view of WO 91/14703, both cited above. The teachings of Oon et al. are discussed above. Oon does not explicitly teach vectors, RNA, and cDNA corresponding to the viral DNA, but Oon et al. point out the importance of further study of the antigenic properties of the Singapore strain HBV vaccine escape mutants (see, e.g., the Abstract; page 702, last paragraph). WO 91/14703 teach cloning and expression of the mutant HBsAg. It would have been obvious to one of ordinary skill in the art to have put the viral DNA taught by Oon et al. into expression vectors as taught by WO 91/14703 in order to have a reliable source of material. One would have been motivated to do so in order to study the relevant antigenic properties as taught by Oon et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032 until 8 January 2004 and 571-272-0913 after that date. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until 26 January 2004 and 571-272-0902 after that date. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Donna C. Wortman', with a stylized flourish at the end.

Donna C. Wortman, Ph.D.
Primary Examiner
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dcw